

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Manne Satyanarayana REDDY et al.

Art Unit: 1626

Application No.: 10/729,856

Examiner: E. O. Sackey

Filed: December 4, 2003

For: POLYMORPHIC FORMS OF DIHYDROCHLORIDE
SALTS OF CETIRIZINE AND PROCESSES
FOR PREPARATION THEREOF

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

RESPONSE

In response to the Office Action that was mailed on May 9, 2006 for the subject application, applicants request consideration of the following traversal of the imposed restriction/election requirement.

The claims of this application were considered as pertaining to two inventions, characterized as follows:

Group I including claims 1-34, 72-73, and 82, to a crystalline form of cetirizine dihydrochloride, and a process for its preparation; and

Group II including claims 35-71 and 74-88, to an amorphous form of cetirizine dihydrochloride and a process for its preparation.

Applicants believe that claims 72, 73, and 82 were erroneously included in Group I, as they relate to the process for preparing amorphous cetirizine dihydrochloride. Further, claims 87 and 88 pertain to compositions of crystalline cetirizine dihydrochloride, and therefore should be included in Group I.

Policy for imposing restriction requirements has been established by M.P.E.P. § 803: "If the search and examination of an entire application can be made without

serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.” For the present application, all of the applicants’ claims 1-88 relate to only a single known chemical compound: [2-[4-[(4-chlorophenyl)-phenyl methyl]-1-piperazinyl]ethoxy] acetic acid dihydrochloride (also named “cetirizine dihydrochloride”). All of claims 1-34 and 87-88 pertain to crystalline cetirizine dihydrochloride, while claims 35-86 all pertain to amorphous cetirizine dihydrochloride. To adequately examine either of these aspects of the invention, it will be necessary to search both of them, since the two searches will be coextensive, so the burden of examining them together cannot possibly be a serious one. The “inventions” of the two groups are classified similarly, as pointed out in the Office Action, and this is an additional indication that there is no separate status in the art for them.

The Office Action states incorrectly that “Groups I-II are drawn to two distinct compounds of cetirizine ...” The only compound recited in the claims is cetirizine dihydrochloride. Aspects being claimed are the crystalline and amorphous forms of dextrorotatory and levorotatory cetirizine dihydrochloride, processes for preparing them, and compositions containing them. Applicants’ claims 1-88 are directed merely to aspects of a single invention.

In view of the foregoing, applicants submit that no restriction can be appropriate for this application. However, if the requirement is being maintained, examination should proceed with the claims of Group I, including claims 1-34, 87, and 88.

If there are any additional matters remaining for completion of this submission, please contact the undersigned.

Respectfully submitted,

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